Nanoscale Materials under TSCA

Briefing for DoD

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Approaches for Nanoscale Materials under TSCA

- Nanoscale materials (NMs) that are “chemical substances” as defined by TSCA are subject to TSCA controls
- NMs not on the TSCA Inventory are “new chemicals”
  - Pre-Manufacture Notice (PMN) required before manufacture
  - OPPT is reviewing PMNs for NMs
- No PMN required for “existing chemical” NMs, i.e., already on the TSCA inventory
- Limited information on whether some NMs may have different toxicity and/or exposure characteristics than their “macro” counterparts
- NM program needs include:
  - A mechanism to collaboratively generate data needed to provide a sound scientific foundation for assessments
  - An appropriate interim approach to obtain better informed decision-making on new chemicals and realize oversight of existing chemical NMs
  - An appropriate degree of industry stewardship in the manufacture and use of new and existing chemical NMs

Public Engagement

- OPPT held a public meeting in June 2005 to obtain public input on how it might best fill its role in assessing/managing the risks of NMs
- OPPT requested its FACA group, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), to provide additional input via a public process
  - NPPTAC "Overview Document" forwarded to EPA for its review/consideration (Nov. 2005)
- Agency Workgroup established in May 2006 to explore the concept of a stewardship program using the above to inform discussion
- Administrator approved a collaborative public process to design a NM Stewardship Program (Sept. 2006)
  - Jim Gulliford invited >500 organizations and agencies to participate (Oct. 2006)

Stewardship Program

- **Step 1 –Collaborative Program Design**
  - Launch open and transparent engagement with stakeholders

    http://epa.gov/oppt/nano/index.htm
  - Release Agency documents for public comment and discussion at public meetings, e.g.,
    - Determining the Inventory status of NMs
    - Concept paper on Stewardship Program
    - Information Collection Request (ICR)
  - Hold public scientific peer consultations on key elements of Stewardship Program
    - Basic risk management practices (Oct. 2006)
    - Characterization information for NMs (2007)

Stewardship Program

- **Step 2 – Implement NM Stewardship Program**
  - Industry Sign-up
    - "Basic" commitment by companies to the elements of Stewardship Program and to provide data on new and existing chemical NMs
    - "In-Depth" commitment by companies/consortia to develop more detailed test data on representative NMs

Stewardship Program

- **Step 3 – Evaluation of Stewardship Program**
  - EPA will evaluate the Stewardship Program after two years in an open and transparent process:
    - Consider need to use TSCA information collection authority to supplement information submitted under Stewardship Program
    - Consider all other data developed for NMs (includes regulatory component)
    - Consider and identify needed next steps:
      - Continue or modify program
      - Take regulatory action (e.g., revisions to PMN reporting form)

Stewardship Program Development Process

- Agency workgroup reviews/develops documents
- EPA Nanotechnology Policy Committee (Office Director level) reviews documents and addresses issues
- Interagency Nanotechnology Policy Coordination Group (NPCG) reviews documents and forwards comments to EPA
- EPA makes changes and completes Agency processes, as appropriate
- Documents released to the public

Stewardship Documents for Upcoming NPCG Review

- NM Stewardship Concept Paper
  - Describes general approach, issues, and considerations for Stewardship Program
  - Includes TSCA Framework on OPPT approach to oversight of nanotechnology under TSCA
- TSCA Inventory Status of Nanoscale Materials
  - Addresses OPPT approach to determining whether a NM is a “new” or “existing” chemical substance under TSCA
- Information Collection Materials
  - Description of information to be collected via the Stewardship Program